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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,632	07/30/2002	Erik D'Hondt	B45201	7231

20462 7590 10/06/2005

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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,632	D'HONDT ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/13/04, 9/3/04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,27,29-34,41-44 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,27,29-34,41-44 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 26, 27, 29-35, 41-44, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection pertains to the "combined dose" limitation of the claims. Applicant argues that the intent is to administer the monovalent vaccine in multiple doses, and the "combined dose" refers to the total amount administered. This would be convincing if the claims were directed to a method of use, but they are not. The claim are directed to a composition of matter, or to a method of producing a composition of matter. To illustrate: imagine 4 identical syringes of vaccine containing 7 ug of hemagglutinin. If I administer syringes 1 and 2 to a patient, applicant owns the content of syringes 1 and 2. If I administer syringe 3 to the same patient, applicant does not own the contents of syringes 1, 2, or 3, because the combined dose is now more than 15 ug. No one can say who owns syringe 4, if I have not decided yet whether or not to use it on the same patient. This is to illustrate how the "combined dose" limitation does not define the metes and bounds of the composition applicant intends to claim (or the method of making the composition).

Claim Rejections - 35 USC § 103

Claims 26, 27, 29-34, 41-44, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Couch et al, Chaloupka et al, and either or both of Schenk et al and Pressler et al (cited in applicant's IDS). The teachings of Couch and Chaloupka have been discussed previously. Schenk and Pressler differ from

the art previously of record in that both teach that an aluminum-adjuvanted influenza vaccine induces equivalent immune response at lower dose compared to a nonadjuvanted vaccine in normal healthy adults. Both references teach that the aluminum-adjuvanted vaccine is superior in persons without previous immunity to the influenza strain used. Therefore, in order to carry out the suggestion of Couch to produce satisfactory immune responses with lower doses of antigen to decrease the burden of vaccine production in a pandemic circumstance, it would have been within the ordinary skill of the art to choose an aluminum-based adjuvant, with reasonable expectation of success.

Claims 44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Couch et al, Chaloupka et al, and either or both of Schenk et al and Pressler et al as applied to claims 26, 27, 29-34, 41-44, 46 above, and further in view of Riberdy et al. As discussed previously, Riberdy teaches that H5N1 virus is thought to have pandemic potential and is being used to develop a vaccine for humans. Therefore it would have been obvious to choose an H5N1 virus for use to vaccinate against a potential pandemic strain.

Conclusion

Applicant's amendment and Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 8/13/2004 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a) and MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/3/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER